

***In re Viagra and Cialis  
Products Liability Litigation***  
**Daubert Hearing**

Plaintiffs' Closing Statement

# Why We Go Forward

The Ninth Circuit has said you should consider “...whether the theory or technique employed by the expert is generally accepted in the scientific community...”




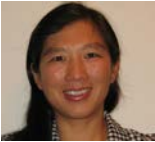


- *Wendell v. GlaxoSmithKline LLC*,  
858 F.3d 1227 (2017)  
(citing *Daubert II*)

The Ninth Circuit has defined that this Court's task "is to analyze not what the experts say, but what basis they have for saying it."

- *Wendell v. GlaxoSmithKline LLC*,  
858 F.3d 1227 (2017)  
(citing *Daubert II*)

“Rule 702 should be applied with a ‘liberal thrust’ favoring admission”

- *Messick v. Novartis*, 747 F.3d 1193 (2014) (citing *Daubert*)

		Qualifications	Data	Methodology	Reliability
	Rizwan Haq, MD, PhD	YES	YES	YES	YES
	Anand Ganesan, MD	YES	YES	YES	YES
	Gary Piazza, PhD	YES	YES	YES	YES
	Feng Liu-Smith, PhD	YES	YES	YES	YES
	Sonal Singh, MD	YES	YES	YES	YES
	Rehana Ahmed- Saucedo, MD, PhD	YES	YES	YES	YES

# *In re Roundup Products Liability Litigation*

“... the plaintiffs’ presentation is that the evidence of a causal link between glyphosate exposure and NHL in the human population seems rather weak. Some epidemiological studies suggest that glyphosate exposure is slightly or moderately associated with increased odds of developing NHL. Other studies, including the largest and most recent, suggest there is no link at all.”

# *In re Roundup Products Liability Litigation*

“However, the question at this phase is not whether the plaintiffs' experts are right. The question is whether they have offered opinions that would be admissible at a jury trial. And the case law—particularly Ninth Circuit case law — emphasizes that a trial judge should not exclude an expert opinion merely because he thinks it's shaky, or because he thinks the jury will have cause to question the expert's credibility. So long as an opinion is premised on reliable scientific principles, it should not be excluded by the trial judge...”

Imanol Arozarena<sup>1</sup> and Claudia Wellbrock<sup>2</sup>

Melanoma is a skin cancer notorious for its metastatic potential. As an initial step of the metastatic cascade, melanoma cells part from the primary tumour

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doi:10

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An important suppressor of melanoma cell invasion is the cGMP-specific phosphodiesterase PDE5A, which removes the cGMP required for  $\text{Ca}^{2+}$  triggered actin-myosin contractility and invasion [60]. In line with such a suppressor role, a follow-up prospective cohort study linked the use of the PDE5 inhibitor sildenafil with an increased risk of melanoma, a correlation still under debate [61].

Research

## Original Investigation

## Use of Phosphodiesterase Type 5 Inhibitors for Erectile Dysfunction and Risk of Malignant Melanoma

Stacy Loeb, MD, MSc; Yasin Folvøval, MSc; Mats Lambe, MD, PhD; David Robinson, MD, PhD; Hans Garma, PhD; Christian Ingvar, MD, PhD; Pir Statin, MD, PhD

Supplemental content at [jama.com](http://jama.com)**IMPORTANCE** The target for the oral erectile dysfunction drugs, phosphodiesterase type 5 (PDE5) inhibitors, is part of a pathway implicated in the development of malignant melanoma. An increased risk of melanoma in sildenafil users was recently reported.**OBJECTIVE** To examine data on:**DESIGN, SETTING, & STUDY** In the Swedish health care register, diagnosed from 21 year of birth.**EXPOSURES** Nium or tadalafil.**MAIN OUTCOMES & RESULTS** Of 4065 inhibitors, as did an increased risk of melanoma (OR, 1.32 [95% CI, 0.95-1.87], 4% [95% CI, 0.95-1.44], 3% for with melanoma stage I (OR, 1.21 [9 through IV (OR, 0 were similar for all with an increased for controls). Men factors that were:**CONCLUSIONS AND ASSOCIATIONS** However, the pattern of prescriptions raised

**Conflict of Interest Disclosures:** All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr Loeb reports receiving personal fees from Bayer and sanofi-aventis. Dr Lambe reports receiving personal fees from Pfizer. Dr Statin reports receiving personal fees from Ferring and AstraZeneca. No other disclosures were reported.

and Brand, Lund University Hospital, Lund, Sweden (Ingvar).

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JAMA. 2015;313(24):2449-2455. doi:10.1001/jama.2015.6604

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**COVINGTON**

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**By Email and Federal Express**

March 12, 2018

Troy Tatling  
Robins Kaplan LLP  
800 LaSalle Avenue  
Suite 2800  
Minneapolis, MN 55402

**Re: In re: Viagra (Sildenafil Citrate) and Cialis (tadalafil)  
Products Liability Litigation  
Dr. Stacey Loeb**

Dear Troy:

Dr. Loeb has been retained through counsel as an expert witness on behalf of Lilly in this multi-district litigation and in its predecessor case, *Chaplain v. Eli Lilly and Company*, No. 3:15-cv-00887 (S.D. Ill.) since June 10, 2016.

NOT POST, CIRCULATED, OR PUBLIC SUBJECT MATTER.

Lilly is unaware of documents or communications between Dr. Loeb and employees of Lilly concerning Dr. Loeb's scientific research regarding PDE5 inhibitors and melanoma. (Lilly believes that its sales representatives may have had routine contact with Dr. Loeb in her role as a practicing urologist.) Insofar as your document requests and interrogatories extend to communications with or documents held by "agents" of Lilly, including counsel, Lilly objects to those requests on the basis of attorney-client privilege and work product protection, as well as under Federal Rule of Civil Procedure 26(b)(4)(D). To the extent that Lilly ultimately determines that Dr. Loeb's opinions may be presented in this litigation, of course, we will make appropriate disclosures under Rule 26(b)(2)(B) and (4)(C).

Sincerely,



Emily Ullman



JNCI / Natl Cancer Inst (2017) 109(8): dx156

doi: 10.1093/jnci/djx156  
First published online August 3, 2017  
Corrigendum

## CORRIGENDUM

**Corrigendum:** "Meta-Analysis of the Association Between Phosphodiesterase Inhibitors (PDE5Is) and Risk of Melanoma" by Stacy Loeb et al. JNCI / Natl Cancer Inst 2017; 109(8): doi:10.1093/jnci/djx156.

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In the eighth paragraph, the second sentence, "Sildenafil use was statistically significantly associated with melanoma (adjusted hazard ratio [HR] = 1.64, 95% CI = 1.04 to 3.22) but not with other skin cancers" should instead read, "Recent sildenafil

The "Notes" section of the paper should include the following sentences: "SL has grants from the NCI, NYS DOH and Prostate Cancer Foundation. SL also has received honoraria for lectures from Boehringer Ingelheim and MDx Health, consulting fees from Lilly, and reimbursed travel to a conference from Minomic."

In the seventh paragraph, the first sentence, "Only low PDE5i exposure was associated with increased risk (RR = 1.15, 95% CI = 1.01 to 1.31), whereas high exposure was not (RR = 1.09, 95% CI = 0.97 to 1.23) (Figure 1)" should instead read "There was no difference in risk between men with low and high exposure to PDE5i (Figure 1)." The third sentence, "High PDE5i exposure was associated with an increased risk of stage 0 melanoma (RR = 1.45, 95% CI = 1.09 to 1.92), but decreased risk of stage II to IV melanoma (RR = 0.67, 95% CI = 0.46 to 0.97)" should instead read, "High PDE5i exposure was associated with an increased risk of stage 0 melanoma (RR = 1.22, 95% CI = 1.00 to 1.49), but not localized or high-stage melanoma."

CI = 0.98 to 1.19; excluding Matthews: RR = 1.11, 95% CI = 0.99 to 1.25; excluding Pottegard (DNHR): RR = 1.06, 95% CI = 0.96 to 1.18; excluding Pottegard (KPNK): RR = 1.15, 95% CI = 1.04 to 1.26." Should instead read: "Test for heterogeneity:  $A_P = .03$ ,  $I^2 = 61.8\%$ ,  $T^2 = 0.0067$ ,  $B_P = .03$ ,  $I^2 = 67.8\%$ ,  $T^2 = 0.0193$ ,  $C_P = .30$ ,  $I^2 = 18.7\%$ ,  $T^2 = 0.0029$ . All statistical tests were two-sided. Summary risk estimate after exclusion of each respective study: excluding Li et al.: relative risk (RR) = 1.10, 95% CI = 1.02 to 1.19; excluding Loeb: RR = 1.09, 95% CI = 0.98 to 1.21; excluding Matthews: RR = 1.12, 95% CI = 0.99 to 1.27; excluding Pottegard (DNHR): RR = 1.15, 95% CI = 1.01 to 1.31; excluding Pottegard (KPNK): RR = 1.16, 95% CI = 1.04 to 1.29."



Dr. Richard  
Marais

YES/NO

Wrong standard for biological  
plausibility



Dr. Lynn-  
Schuchter

YES/NO

Deposition testimony confirms that  
she deferred to other defense  
experts on biological plausibility  
She is not an epidemiologist, and did  
not perform a Bradford Hill analysis



Dr. Boris  
Bastian

YES/NO

Causation opinion  
Wrong standard for biological  
plausibility



Dr. John  
Witte

YES

Stayed in his lane